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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,412	03/09/2001	Harry W. Schmidt	T268.12-0047	4806
26285	7590	03/17/2005		
KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP 535 SMITHFIELD STREET PITTSBURGH, PA 15222				
			EXAMINER	
			CROSS, LATOYA I	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/803,412	Applicant(s) SCHMIDT ET AL.	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-11 and 13-16 is/are rejected.
- 7) ☒ Claim(s) 7 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 21, 2004 has been entered.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 9-11 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,713,974 to Stone.

Stone teaches an autosampler comprising *inter alia*, a needle assembly. The needle assembly comprises a sampling needle (260) adapted to pierce the septum of a vial (77). The autosampler also comprises a vial stabilizer (320), equivalent to Applicants' claimed sealing boot, which engages the top of vial (77) as it is lifted toward needle (260). See col. 6, lines 22-27). As shown in figure 4, the vial stabilizer engages the vial septum when the vial is engaged with needle. With respect to claim 2, the arm (325), in conjunction with the vial stabilizer, serve as an ejector tab because when the arm (325) moved downward on the guide rod, the arm, in conjunction with the vial stabilizer, urge the vial away from the needle. With respect to

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claim 9, the vial stabilizer would inherently limit leakage between the needle and the septum because the needle would have to pass back through the stabilizer to exit completely. With respect to claim 10, figure 3 shows the vial stabilizer being disposed at a proximate end of the tip of the needle. With respect to claim 11, figures 4 and 8 show a needle housing (280), which has a structure at its lower end coupled to arm (300). This feature is equivalent to Applicant's claimed needle block because it the vial stabilizer, when lifted by a vial on the vial lifter, cannot move up the guide rod any further than this lower portion of the needle housing. Likewise, with respect to claim 14, where the vial stabilizer is lifted up to its maximum point (where the vial stabilizer contacts the lower portion of the needle housing), a seal is created between the needle housing, the vial and the vial stabilizer. With respect to claims 15 and 16, Stone teaches that the vial is lifted up toward the sampling needle (260) so as to bring the needle into contact with vial (77). Then, the vial stabilizer (320) engages the septum of the vial.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Stone.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone in view of US Patent 5,632,895 to Tsukagoshi et al.

The disclosure of Stone is described above. Stone fails to teach the material used for the vial stabilizer and the hardness of the material.

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Tsukagoshi et al teach a blood collecting assembly whereby a blood sample is removed from a vial containing the sample using a syringe. Tsukagoshi et al teaches the importance of the material in the vial through which the needle moves with respect to the seal that exists at the mouth of the vial. Specifically, Tsukagoshi et al teach that the material at the mouth of the vial should be a rubber material, such as silicone rubber, having a hardness of 30-60.

Tsukagoshi et al explain that this material easily permits the penetration of the needle into the vial and allows resealing after the needle is removed to maintain the sealed environment.

It would have been obvious to one of ordinary skill in the art to use silicone rubber as the material for the vial stabilizer in Stone because the silicone rubber material would enhance the seal between the needle and the vial and thus prevent contamination of the vial contents.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious within the meaning of 35 USC 103 in view of the teachings of Stone and Tsukagoshi et al.

***Allowable Subject Matter***

5. Claims 7 and 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 7 and 8 recite a sealing boot having an upper and lower plate, a first gasket sealing between the upper plate and the ejector tab and second gasket sealing between the lower plate and ejector tab. The prior art of record fails to teach or suggest a sealing boot having an upper and lower plate and first and second gasket sealings.

*Response to Arguments*

6. Applicant's arguments filed December 21, 2004 have been fully considered but they are not persuasive. In response to the anticipatory rejection over Stone and the obviousness rejection over Stone in view of Tsukagoshi et al, Applicants argue that the vial stabilizer taught by Stone is not equivalent to the sealing boot instantly claimed. Applicants assert that the vial stabilizer of Stone cannot cause a seal between the vial stabilizer and the vial.

In response, the Examiner disagrees that the device taught by Stone differs from that of the instantly claimed invention. Stone teaches that the vial stabilizer is designed to receive and engage the top of a vial (col. 6, lines 22-27). Stone further teaches that after the vial top engages the vial stabilizer, the needles (260,270) penetrate the vial septum (78).

Applicants point to the teaching in Stone that the vial stabilizer has a central aperture allowing it to move freely with respect to the inner and outer needles and assert that this teaching prevents any seal from forming between the vial stabilizer and a vial. It is unclear, however, how Applicants can draw such a conclusion from this teaching. In comparing the instant invention to that taught by Stone, both devices have the structures and operate in the same manner. In the instant invention, there exists an aperture in the sealing boot that will allow the needle (556) to move freely through the sealing boot. Compare figure 2 of instant application, where sealing boot is located at the bottom of the needle to figure 3 of the instant application, where the needle protrude through the sealing boot into the vial. See also, figure 3 of Stone where the vial stabilizer is located at the bottom of the needle and figure 4, where the needle protrudes through the sealing boot and into the vial. Figure 4 of Stone clearly shows that the vial is completely engaged with the vial stabilizer.

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It appears that Applicants rely on their sealing boot (558) in combination with needle block (574) to support their claim of a "seal". However, the needle block feature is not a part of the instant claims. The Examiner understands Applicants' argument that according to the disclosure of Stone and figure 4 of Stone, the vial stabilizer (320) never reaches needle housing (280). However, the needle housing of Stone would be equivalent to the needle block of the instant invention, which is not claimed.

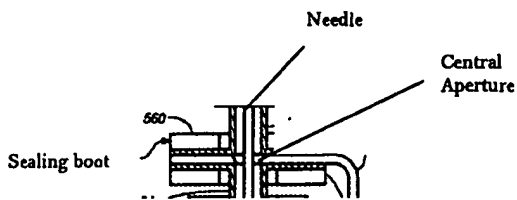


Figure 3 (partial) of instant invention

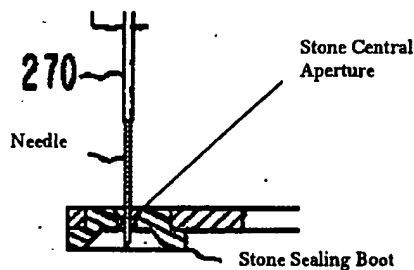


Figure 3 (partial) of Stone

Furthermore, according to the specification, Applicants' sealing boot is depicted by reference character (558), which is shown as a structure disposed about the sampling needle and having a central aperture through which the needle may move. Stone shows the same structure surrounding the sampling needle and having a central aperture through which the needle may

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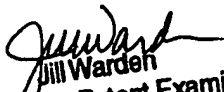
move. Thus, although Stone may not disclose the vial stabilizer as a "sealing boot", the structures are the same.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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